

10-12-04

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Patent Application of:

Applicant: Minshall, *et al.*

Serial No.: 10/016,528

Filed: October 30, 2001

Title: *Anti-Tumor Vaccine*

Group Art Unit: 1642

Examiner: Yaen, Christopher

Certificate of Mailing Under C.F.R. §1.8

I hereby certify that this correspondence and all marked attachments are being deposited by Express Mail, Express Mailing Label No.:EV 517729976 US on 7-Oct-04 addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By:

Vicki L. Andrews

Vicki L. Andrews

10/13/2004 HALI11 00000004 232415 10016528
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PETITION UNDER 37 C.F.R. § 1.182

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

CancerVax Corporation ("CancerVax"), located at 2110 Rutherford Road, Carlsbad, CA 92008, is, by way of written assignment, a partial assignee of record of the application for letters patent identified above ("the Application"). As a partial assignee and co-owner of the Application, CancerVax hereby petitions the Commissioner for permission under MPEP § 402.10 to participate in the prosecution of the Application, and to appoint the law firm of Wilson, Sonsini Goodrich and Rosati as its attorneys/agents to prosecute the Application and to transact at business at the Patent and Trademark Office connected therewith. This request is being made so that CancerVax may protect its co-ownership rights in the Application. This request is particularly urgent in that the other co-owners have indicated an intention to abandon the Application. Thus, unless CancerVax is permitted to participate in the prosecution, its rights in the Application could be forever lost.

MPEP § 402.10 provides that the Patent Office may accept powers of attorney when signed by less than all of the applicants or owners of the application if they are accompanied by a petition and fee under 37 C.F.R. § 1.182 giving good and sufficient reasons as to why such papers should be accepted. As shown in more detail below, good and sufficient reasons exist in this case for allowing CancerVax to participate in the prosecution of the Application.

CancerVax should be allowed to participate in the prosecution of the Application because it is a partial assignee and co-owner of the Application, and the other current co-owners have indicated an intention to abandon the application. The Application named four inventors: Bill Minshall, Suzanne Minshall, Michael Skotzko and John Conner. On August 31, 2004, John Conner assigned his rights in the Application to CancerVax, thereby making CancerVax a partial assignee. *[A copy of this written assignment and recordation is attached hereto as Exhibit 1.]* Shortly thereafter, on September 16, 2004, CancerVax was informed by Matthew Newboles, the current attorney-of-record, that he was under instructions from his client to abandon the Application. Requests to Mr. Newboles for information about these instructions have gone unanswered. CancerVax does not wish the Application to be abandoned at this time.

There is an outstanding Office Action which was mailed on May 25, 2004 and must be responded to by November 25, 2004, or the application will go abandoned. *[A copy of the May 25, 2004 Office Action is attached as Exhibit 2.]* Therefore, its only recourse is this Petition for permission to participate in the prosecution of the Application. CancerVax believes that this constitutes good and sufficient reasons as to why it should be permitted to participate in the prosecution.

For these reasons, CancerVax respectfully requests that this petition be granted, that CancerVax be permitted to participate in the prosecution of this Application, and that the accompanying Power of Attorney be accepted.

Respectfully submitted,



Mary Ann Stretch
Sr. Dir. IP
CancerVax Corporation

Date: 7-Oct-04

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

ASSIGNMENT OF APPLICATION

Docket Number

Whereas, the undersigned:

1. Conner, John
Sherman Oaks, CA

2.

3.

4.

hereinafter termed "Inventors", have invented certain new and useful improvements in

ANTI-TUMOR VACCINE

☒ for which an application for United States Patent was filed on October 30, 2001, Application No. 10/016,528 and including United States Patent Application Publication No. US 2003/0082136 A1, published on May 1, 2003.☐ for which a United States Patent issued on __, U.S. Patent No. __.

WHEREAS, CancerVax Corporation, a corporation of the State of Delaware, having a place of business at 2110 Rutherford Road, Carlsbad, California, 92008, (hereinafter termed "Assignee"), is desirous of acquiring the entire right, title and interest in and to said application and the invention disclosed therein, and in and to all embodiments of the invention, heretofore conceived, made or discovered jointly or severally by said Inventors (all collectively hereinafter termed "said invention"), and in and to any and all patents, inventor's certificates and other forms of protection (hereinafter termed "patents") thereon granted in the United States and foreign countries.

NOW, THEREFORE, in consideration of good and valuable consideration acknowledged by said Inventors to have been received in full from said Assignee:

1. Said Inventors do hereby sell, assign, transfer and convey unto said Assignee the entire right, title and interest (a) in and to said application and said invention; (b) in and to all rights to apply for foreign patents on said invention pursuant to the International Convention for the Protection of Industrial Property or otherwise; (c) in and to any and all applications filed and any and all patents granted on said invention in the United States or any foreign country, including each and every application filed and each and every patent granted on any application which is a divisional, substitution, continuation, or continuation-in-part of any of said applications; and (d) in and to each and every reissue or extensions of any of said patents.

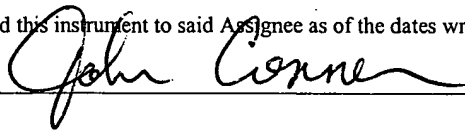
2. Said Inventors hereby jointly and severally covenant and agree to cooperate with said Assignee to enable said Assignee to enjoy to the fullest extent the right, title and interest herein conveyed in the United States and foreign countries. Such cooperation by said Inventors shall include prompt production of pertinent facts and documents, giving of testimony, execution of petitions, oaths, specifications, declarations or other papers, and other assistance all to the extent deemed necessary or desirable by said Assignee (a) for perfecting in said Assignee the right, title and interest herein conveyed; (b) for prosecuting any of said applications; (c) for filing and prosecuting substitute, divisional, continuing or additional applications covering said invention; (d) for filing and prosecuting applications for reissuance of any said patents; (e) for interference or other priority proceedings involving said invention; and (f) for legal proceedings involving said invention and any applications therefor and any patents granted thereon, including without limitation reissues and reexaminations, opposition proceedings, cancellation proceedings, priority contests, public use proceedings, infringement actions and court actions; provided, however, that the expense incurred by said Inventors in providing such cooperation shall be paid for by said Assignee.

3. The terms and covenants of this assignment shall inure to the benefit of said Assignee, its successors, assigns and other legal representatives, and shall be binding upon said Inventors, their respective heirs, legal representatives and assigns.

4. Said Inventors hereby jointly and severally warrant and represent that they have not entered and will not enter into any assignment, contract, or understanding in conflict herewith.

IN WITNESS WHEREOF, said Inventors have executed and delivered this instrument to said Assignee as of the dates written below:

Date:

31 Aug 04

Date:

Date:

Date:

CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT

State of California

County of

San Diego

} ss.

On August 31, 2004, before me, Joan Marie Sonner, Notary Public

Date

Name and Title of Officer (e.g., "Jane Doe, Notary Public")

personally appeared John Conner

Name(s) of Signer(s)

- ☒ personally known to me
☐ proved to me on the basis of satisfactory evidence

to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.



WITNESS my hand and official seal.

Joan Marie Sonner

Signature of Notary Public

Place Notary Seal Above

OPTIONAL

Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document.

Description of Attached Document

Title or Type of Document: _____

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

Capacity(ies) Claimed by Signer

Signer's Name: _____

- ☐ Individual
☐ Corporate Officer — Title(s): _____
☐ Partner — ☐ Limited ☐ General
☐ Attorney in Fact
☐ Trustee
☐ Guardian or Conservator
☐ Other: _____

Signer Is Representing: _____

RIGHT THUMBPRINT
OF SIGNER

Top of thumb here.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231



700112052A

SEPTEMBER 10, 2004

PTAS

WILSON SONSINI GOODRICH, ET AL.
JEFFREY W. GUISE
650 PAGE MILL ROAD
PALO ALTO, CA 94304

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 09/02/2004

REEL/FRAME: 015103/0670

NUMBER OF PAGES: 2

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

CONNER, JOHN

DOC DATE: 08/31/2004

ASSIGNEE:

CANCERVAX CORPORATION
2110 RUTHERFORD ROAD
CARLSBAD, CALIFORNIA 92008

SERIAL NUMBER: 10016528

FILING DATE: 10/30/2001

PATENT NUMBER:

ISSUE DATE:

TITLE: ANTI-TUMOR VACCINE

015103/0670 PAGE 2

DIANA NGUYEN, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS



AT

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,528	10/30/2001	Bill Minshall	MINSH-001A	9635
7663	7590	05/25/2004		
STETINA BRUNDA GARRED & BRUCKER 75 ENTERPRISE, SUITE 250 ALISO VIEJO, CA 92656			EXAMINER YAEN, CHRISTOPHER H	
			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



Office Action Summary

Application No.	Applicant(s)	
10/016,528	MINSHALL ET AL.	
Examiner	Art Unit	
Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-7,10,11 and 13-39 is/are pending in the application.
- 4a) Of the above claim(s) 2,5-7,10,11 and 18-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,13,14,16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2/22/02 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I in Paper No. 11/06/2003 is acknowledged.
Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 3-4, 8-9, and 12 are canceled without prejudice or disclaimer.
3. Claims 1-2, 5-7, 10-11, and 13-39 are pending, claims 2, 5-7, 10-11, and 18-39 are withdrawn from further consideration as being drawn to non-elected subject matter.
4. Claims 1, 13-14, and 16-17 are examined on the merits.

Information Disclosure Statement

5. The Information Disclosure Statement filed 2/22/2002 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections - 35 USC § 112

6. Claims 1-2, 14, and 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. With regard to claim 1 and dependent claims thereof in the recitation of the term "comprising" as it pertains to GM-2, GM-CSF, and HSP-90, it is indefinite because it is

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unclear as to whether GM-2, GM-CSF, and HSP-90 are parts of a larger complex or molecule.

8. With regard to claim 17 in the recitation of the phrase "said mammal comprises a canine", it is unclear as to what mammal is being claimed. Does the applicant intend for the said mammal to be a mixture of a canine and something else? Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 13, 14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoo WS (US Patent 5,891,432). Hoo WS teaches a cellular vaccine or composition that comprises an allogeneic cancer cell or tumor cell line that comprises a tumor associated ganglioside (column 9, line 27; column 10, lines 20-25 (cell lines); column 20, line 17-27), GM-CSF cytokine (columns 6, lines 58-67, column 7, lines 1-8), and a HSP-90 heat shock protein (column 6 lines 35-37). The cancer cell lines taught by Hoo WS inherently comprise gangliosides on its surface, such as GM-2 (see Fredman P *et al* Biochim Biophys Acta 1990 Aug;1045(3):239-44 or Maeda Y *et al* Cancer Biochem Biophys 1998 Nov; 16(4):313-32 as further evidence of surface expression of ganglioside GM-2 on recited tumor cells). Hoo WS *et al* further teach the limitations of

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using bacterial adjuvants such as BCG (column 12, lines 28-35) and that the cell lines can be irradiated (column 25, lines 47-49).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoo WS in view of Hogge GS *et al* (Cancer Gene Therapy 1999;6(1):26-36). Claims are drawn to a composition for the induction of an immune response in a mammal, wherein the composition comprises an allogeneic cancer cell providing a tumor associated ganglioside GM-2, a GMCSF cytokine, and a HSP-90 heat shock protein (claim 1); wherein the composition further comprises a bacterial adjuvant (claim 13), wherein the adjuvant is BCG (claim 14); wherein the allogeneic cell line is rendered incapable of proliferation by radiation (claim 16); and wherein the mammal comprises a canine and said allogeneic cell is a canine cancer cell line (claim 17).

Hoo WS teaches a cellular vaccine or composition that comprises an allogeneic cancer cell or tumor cell line that comprises a tumor associated ganglioside (column 9, line 27; column 10, lines 20-25 (cell lines); column 20, line 17-27), GM-CSF cytokine (columns 6, lines 58-67, column 7, lines 1-8), and a HSP-90 heat shock protein (column 6 lines 35-37). The cancer cell lines taught by Hoo WS inherently comprise

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gangliosides on its surface, such as GM-2 (see Fredman P *et al* Biochim Biophys Acta 1990 Aug;1045(3):239-44 or Maeda Y *et al* Cancer Biochem Biophys 1998 Nov; 16(4):313-32 as further evidence of surface expression of ganglioside GM-2 on recited tumor cells). Hoo WS *et al* further teach the limitations of using bacterial adjuvants such as BCG (column 12, lines 28-35) and that the cell lines can be irradiated (column 25, lines 47-49). However, Hoo WS fails to specifically characterize the type of mammal or that the cancer cell line be derived from a canine cancer cell.

The deficiency of Hoo WS is made up by Hogge *et al*, wherein a cancer cell composition or vaccine, that is derived from canine cancer cells, is used in a canine subject.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising a canine cancer cells wherein the said cell comprises GM-2 gangliosides, GMCSF cytokine and HSP-90 for the induction of an immune response in a canine. The Hogge *et al* reference is reasonably relevant to the skilled artisan because it taught that the use of a irradiated canine cancer cell line were useful in the induction of an immune response especially in an anti-neoplastic capacity for tumorigenic canine subjects. Therefore, one of ordinary skill in the art would have had motivation in combining the references because both Hoo WS and Hogge *et al* taught compositions that were capable of inducing immune responses against tumors in mammalian subjects, wherein the compositions comprised cancer cell vaccines. One of skill in the art would have had reasonable expectation of success in using allogeneic canine cancer cells for the induction of an immune

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response in a mammal wherein the composition comprises a GM-2 ganglioside, a GMCSF cytokine, and HSP-90 because Hogge *et al* specifically stated that the use of such cells could prove to be a valuable translational research model and because the canine cancer cells displayed anti-neoplastic effects. The combination of other components such as GM-2 gangliosides and HSP-90 would only further enhance the specificity of the immunological effects.

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
January 29, 2004


YVONNE EYLER, Ph.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600